UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: August 10, 2009

SUBJECT: Science review in support of the registration of Fleischmann's Vinegar Weed Control, containing 20.0% Acetic Acid As Its Active Ingredient.

Decision Number:	**409440**
DP Number:	**366234**
EPA File Symbol Number:	**85208-R**
Chemical Class:	**Biochemical**
PC Code:	**044001**
CAS Number:	**64-19-7**
Active Ingredient Tolerance Exemptions:	**N/A; Non Food Use**
MRID Numbers:	**477447-01 to -04**

FROM: Jacob Moore, Chemist /s/ 08/10/09 8/10/09
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Leonard Cole, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

THE FOLLOWING CONTAINS CONFIDENTIAL BUSINESS INFORMATION

ACTION REQUESTED

Fleischmann's Vinegar Company, Inc. requests registration of Fleischmann's Vinegar Weed Control, which is intended for use as an herbicide on various weed grasses. In support of this registration, the registrant has submitted product chemistry data in MRIDs 477447-01 and -02 and waiver rationale in MRIDs 477447-03 and -04.

[redacted]

Inert ingredient information may be entitled to confidential treatment

RECOMMENDATIONS AND CONCLUSIONS

1. CSF dated 5/11/09 is **UNACCEPTABLE, but upgradable upon specification of** the name and address of the supplier of [redacted]

2. Product Chemistry data are **ACCEPTABLE. No additional data are required.**

3. Tier I Toxicity data are **ACCEPTABLE. No additional data are required.**

4. Tier I Non-Target data are **ACCEPTABLE. No additional data are required.**

Note to RAL:

1. While reading the product chemistry MRID (47747701) it is confusing as to what product is being analyzed for the preliminary analysis. Is the analyzing Fleischmann's White Distilled Vinegar and proposing a 20% AI concentration or does Fleischmann's Vinegar Weed Control have an AI concentration of 20%? Or, are the two names interchangeable for the same formulation? If so, the registrant must adjust the name of the AI on the CSF to "Acetic acid" solely.

STUDY SUMMARIES

Product Description

Fleischmann's Vinegar Weed Control is an end-use product for non-selective control of herbaceous broadleaf weeds and weed grasses on residential, non-crop, right-of-way, and industrial land sites.

Product Chemistry

Refer to the Data Evaluation Record (DER). Viscosity was addressed by the registrant for the TGAI (Acetic Acid). This is acceptable for satisfying the data requirement. Preliminary analysis data was submitted for three batches. This is adequate for satisfying the data requirement.

Toxicity

Literature sources were cited by the registrant for the Tier I Toxicity Data. These sources are acceptable to satisfy the data requirements. The data is summarized in the table below. Refer to the Data Evaluation Record (DER).

Acetic Acid
PC Code: 044001

DP Number: 366234
EPA Reg. No.: 85208-R

Study Type/OPPTS Guideline	LD_{50}/LC_{50}/Results	Toxicity Category	MRID
Acute Oral Toxicity/OPPTS 870.1100	4960 mg/kg	III	47744703
Acute Dermal Toxicity/OPPTS 870.1200	1060 mg/kg	II	47744703
Acute Inhalation Toxicity/OPPTS 870.1300	11.4 mg/L	IV	47744703
Acute Eye Irritation/OPPTS 870.2400	Low pH, not required	N/A	47744703
Acute Dermal Irritation/OPPTS 870.2500	Low pH, not required	N/A	47744703
Skin Sensitization/OPPTS 870.2600	Not a sensitizer		47744703

Non-Targets

Literature sources were cited by the registrant for the Nontarget Data. These sources are acceptable to satisfy the data requirements. Refer to the Data Evaluation Record (DER).

cc: J. Moore, L. Cole, BPPD Science Review File, IHAD/ARS
J. Moore, FT, PY-S: 08/10/09

Acetic Acid
PC Code: 044001

DP Number: 366234
EPA Reg. No.: 85208-R

DATA EVALUATION RECORD

ACETIC ACID
(Fleischmann's Vinegar Weed Control)

STUDY TYPES: Product Identity and Composition (OPPTS 880.1100)
Description of Starting Materials, Production and Formulation Process (OPPTS 880.1200)
Discussion of Formation of Impurities (OPPTS 880.1400)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)

MRIDs 47744701-02

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 09-025

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: _____
Date: _____

Secondary Reviewers:
Sylvia Milanez, Ph.D., D.A.B.T.

Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____
Date: _____

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
Date: _____

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Product Identity and Composition (OPPTS 880.1100) Description of Starting Materials, Production and Formulation Process (OPPTS 880.1200) Discussion of Formation of Impurities (OPPTS 880.1400) Preliminary Analysis (OPPTS 830.1700) Certified Limits (OPPTS 830.1750) Enforcement Analytical Method (OPPTS 830.1800) Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)
MRID NOS:	47744701-02
DECISION NO:	409440
DP BARCODE:	DP365094
TEST MATERIAL:	Fleischmann's Vinegar Weed Control (a.i., 20.00 % w/w acetic acid)
PROJECT STUDY NO:	MRIDs 47744701-02: Not applicable
SPONSOR:	Fleischmann's Vinegar Co., Inc., 12604 Hiddencreek Way, Cerritos, CA 90703
TESTING FACILITY:	MRIDs 47744701-02: Not applicable
TITLE OF REPORT:	MRID 47744701: Fleischmann's Vinegar Weed Control: Product Identity, Composition and Analysis MRID 47744702: Fleischmann's Vinegar Weed Control: Physical-Chemical Characteristics
AUTHOR:	MRIDs 47744701-02: Norton, S.
STUDY COMPLETED:	MRIDs 47744701-02: May 1, 2009
CONFIDENTIALITY CLAIMS:	MRID 47744701: Confidential information is contained in a confidential appendix. MRID 47747702: None.
GOOD LABORATORY PRACTICE:	MRID 47744701: A signed and dated GLP statement was included. The data volume is not a laboratory study, and is not subject to the requirements of 40 CFR Part 160. MRID 44747702: A signed and dated GLP statement was included. The submitter did not sponsor or conduct the study, and does not know it was conducted in accordance with 40 CFR Part 160.
CONCLUSION:	Fleischmann's Vinegar Weed Control (white distilled vinegar) is an end use product for non-selective control of herbaceous broadleaf weeds and weed grasses on residential, non-crop, right-of-way, and industrial land sites. It is identical to the registered product [redacted]. The active ingredient is 20.00% w/w acetic acid (given as 20.0% on the product label). Impurities associated with the active ingredient are [redacted] and [redacted] The inert ingredient is [redacted]. The specific

source for the [redacted] is not identified on the CSF. The starting materials are described, but the constituents of a proprietary material are not provided. The amounts of the starting materials used in the formulation process, the process equipment and conditions, the quality control process, and the product packaging are not described. Results from a preliminary analysis were provided for only three batches of the product. The certified limits for the nominal concentrations of the active and inert ingredients are within the OPPTS 830.1750 recommended ranges. The enforcement analytical method is acid-base titration. Acceptable chemical and physical properties were provided, with the exception that no data were provided for viscosity.

CLASSIFICATION: **Unacceptable**, but upgradeable if 1) the specific [redacted] supply for [redacted] is provided on the CSF; 2) the amounts of the ingredients are given to the same number of decimal places on the CSF and product label; 3) the constituents of the [redacted] starting material are identified; 4) the formulation process equipment and conditions, the quality control process, and the product packaging are described; 5) results from a preliminary analysis of two additional batches are provided; and 6) the viscosity of the product is provided.

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Test Material: Fleischmann's Vinegar Weed Control (a.i., 20.00 % w/w acetic acid)

I. **PRODUCT IDENTITY AND COMPOSITION:** Fleischmann's Vinegar Weed Control (white distilled vinegar) is an end use product for non-selective control of herbaceous broadleaf weeds and weed grasses on residential, non-crop, right-of-way, and industrial land sites. It is identical to the registered product [redacted]). The active ingredient is 20.00% w/w acetic acid (given as 20.0% on the product label). Impurities associated with the active ingredient are [redacted]. The inert ingredient is [redacted] The specific [redacted] supply is not identified on the CSF. The concentrations of the ingredients are given to two decimal places on the CSF and to one decimal place on the product label. On p. 4 of the confidential appendix to MRID 47744701, the registrant certifies that the product is food grade and GRAS.

Deficiencies: The specific [redacted] supply for the [redacted] used must be identified on the CSF. The weight percent of the ingredients must be given to the same number of decimal places on the CSF and the product label.

II. **DESCRIPTION OF STARTING MATERIALS AND FORMULATION PROCESS:** The starting materials for Fleischmann's Vinegar Weed Control are [redacted] MSDSs

Inert ingredient information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

were supplied for [redacted] and [redacted] and a specification sheet was supplied for [redacted]

[redacted]

III. **DISCUSSION OF FORMATION OF IMPURITIES:** The impurities in the product are identified on the CSF. Fleischmann's Vinegar Weed Control is produced using dedicated equipment, and there is no cross-contamination from other products.

Deficiencies: None.

IV. [redacted]

Quality control process information may be entitled to confidential treatment

V. **CERTIFIED LIMITS:** Table 1 lists the nominal concentrations and certified limits for the ingredients in Fleischmann's Vinegar Weed Control as given on the CSF. The certified limits for the nominal concentrations of the active and inert ingredients are within the OPPTS 830.1750 recommended ranges.

TABLE 1. Nominal CSF concentrations and certified limits for Fleischmann's Vinegar Weed Control[a]

Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
Active Ingredient					
Fleischmann's White Distilled Vinegar Acetic acid (64-19-7)	044001	Active ingredient	20.00	19.40	20.60
[redacted]					

[a]Data from CSF

Deficiencies: None.

VI. **ENFORCEMENT ANALYTICAL METHOD:** The enforcement analytical method for determining the active ingredient in Fleischmann's Vinegar Weed Control is acid-base titration. The method (Vinegar Institute VIN010) is detailed on pp. 7-8 of MRID 47744701. A 10 mL sample is pipetted into a 250 mL Erlenmeyer flask and approximately 20 mL of distilled water and 2 drops of phenolphthalein solution are added. The solution is then titrated with 1N NaOH solution to the endpoint (a faint pink persists for 30 seconds) and the grain strength is read from a standard table.

Deficiencies: None.

VII. **PHYSICAL AND CHEMICAL CHARACTERISTICS:**

1. **Methods**: Methods for determining the applicable physical and chemical characteristics of Fleischmann's Vinegar Weed Control are provided in Table 2.

2. **Results**: The physical/chemical characteristics of Fleischmann's Vinegar Weed Control are provided in Table 2. Viscosity for the EP was not provided.

3. **Deficiencies:** The viscosity of the EP must be provided.

TABLE 2. Physical and Chemical Properties for Fleischmann's Vinegar Weed Control[a]

Guideline Reference No./Property		Description of Result	Methods
830.6302	Color	Acetic acid = colorless EP = colorless	Public literature Product data sheet
830.6303	Physical State	Acetic acid = liquid or crystals EP = liquid	Public literature MSDS
830.6304	Odor	Acetic acid = pungent EP = pungent, characteristic of white distilled vinegar	Public literature MSDS
830.6313	Stability	Acetic acid = attacks many metals Not required for EP	Public literature
830.6314	Oxidation/Reduction: Chemical Incompatibility	Acetic acid = incompatible with strong oxidizers, strong caustics EP = stable, but avoid strong oxidizers and caustics	Public literature MSDS
830.6315	Flammability	Acetic acid (glacial) = 103°F (closed cup) EP = not flammable	Public literature MSDS
830.6316	Explodability	Acetic acid = above 39°C explosive vapor/air mixtures may be formed EP = not explosive	Public literature Product data sheet
830.6317	Storage Stability	EP = 24 months	Product data sheet
830.6319	Miscibility	Acetic acid = miscible EP = miscible	Public literature
830.6320	Corrosion Characteristics	Acetic acid = highly corrosive in concentrated form; corrodes metals and some coatings, plastics, and rubber EP = Not corrosive to packaging.	Public literature Product knowledge
830.6321	Dielectric Breakdown Voltage	Acetic acid and EP = not applicable, not for use around electrical equipment.	
830.7000	pH	EP = 2.25	Product data sheet
830.7100	Viscosity	Acetic acid = 1.22 mPa/s at 25°C **Not provided for EP**	Public literature
830.7200	Melting Range	Acetic acid = 16.6°C Not required for EP	Public literature
830.7220	Boiling Range	Acetic acid = 244°F EP = 215°F (100 grain)	Public literature
830.7300	Density/Relative Density/Bulk Density	Acetic acid specific gravity = 1.05 at 20°C EP density = 8.55 lbs/gallon (200 grain) at 20°C	Public literature Product data sheet
830.7370	Dissociation Constant in Water	Acetic acid = 4.76 pKa at 25°C Not required for EP	Public literature
830.7550	Partition Coefficient	Acetic acid = log Pow -0.31 Not required for EP	Public literature
830.7840	Water Solubility	Acetic acid = 1.00 x 10^6 mg/L at 25°C EP = Completely soluble	Public literature MSDS
830.7950	Vapor Pressure	Acetic acid: 1.5 kPa at 20°C Not required for EP	Public literature

VIII. ADDITIONAL REVIEWER'S COMMENTS: None.

Acetic Acid
PC Code: 044001

DP Number: 366234
EPA Reg. No.: 85208-R

DATA EVALUATION RECORD

ACETIC ACID
(Fleischmann's Vinegar Weed Control)

STUDY TYPE: Waiver Requests for Biochemical Pesticide Data Requirements

MRID 47744703

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 09-025

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: _____
Date: _____

Secondary Reviewers:
Sylvia Milanez, Ph.D., D.A.B.T.

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Robert H. Ross, M.S., Group Leader

Signature: _____
Date: _____

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
Date: _____

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DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Waiver Requests for Biochemical Pesticide Data Requirements
MRID NO:	47744703
DECISION NO:	409440
DP BARCODE:	DP365094
TEST MATERIAL:	Fleischmann's Vinegar Weed Control (a.i., 20.00 % w/w acetic acid)
PROJECT STUDY NO:	Not applicable
SPONSOR:	Fleischmann's Vinegar Co., Inc., 12604 Hiddencreek Way, Cerritos, CA 90703
TESTING FACILITY:	Not applicable
TITLE OF REPORT:	Fleischmann's Vinegar Weed Control: Human Health Assessment
AUTHOR:	Norton, S.
STUDY COMPLETED:	May 1, 2009
CONFIDENTIALITY CLAIMS:	None.
GOOD LABORATORY PRACTICE:	A signed and dated GLP statement was included. The report is not a laboratory study and is not subject to the requirements of 40 CFR Part 160.
CONCLUSION:	Sufficient information was submitted to support the requested waivers for Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation Toxicity, Primary Eye Irritation, Primary Dermal Irritation, Dermal Sensitization, 90-Day Oral Toxicity, 90-Day Dermal Toxicity, 90-Day Inhalation Toxicity, Prenatal Development (Tier I), Bacterial Reverse Mutation Testing, *In vitro* Mammalian Cell Assay, *In vitro* Mammalian Cytogenetics, Prenatal Development (Tier II), Immunotoxicity, Dermal Outdoor Exposure, Dermal Indoor Exposure, Inhalation Outdoor Exposure, Inhalation Indoor Exposure, Biological Monitoring, Immune Response, Reproduction and Fertility Effects, Chronic Oral Toxicity, Carcinogenicity, Mammalian Spermatogonial Chromosome Aberration Testing, and Companion Animal Safety for Fleischmann's Vinegar Weed Control. Any hypersensitivity incidents will be reported by the registrant.

Product Description

Fleischmann's Vinegar Weed Control (white distilled vinegar) is an end use product for non-selective control of herbaceous broadleaf weeds and weed grasses on residential, non-crop, right-of-way, and industrial land sites. The active ingredient is 20.00% w/w acetic acid. Impurities associated with the active ingredient are [redacted] and [redacted]. The inert ingredient is [redacted]

Inert ingredient information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

Acetic Acid
PC Code: 044001

DP Number: 366234
EPA Reg. No.: 85208-R

Waiver Request

The registrant is requesting waivers for the following studies:

Tier I Studies

Acute Oral Toxicity	(OPPTS 870.1100)
Acute Dermal Toxicity	(OPPTS 870.1200)
Acute Inhalation Toxicity	(OPPTS 870.1300)
Primary Eye Irritation	(OPPTS 870.2400)
Primary Dermal Irritation	(OPPTS 870.2500)
Dermal Sensitization	(OPPTS 870.2600)
Hypersensitivity	(None)
90-Day Oral Toxicity	(OPPTS 870.3100)
90-Day Dermal Toxicity	(OPPTS 870.3250)
90-Day Inhalation Toxicity	(OPPTS 870.3465)
Prenatal Development	(OPPTS 870.3700)
Bacterial Reverse Mutation Testing	(OPPTS 870.5100)
In vitro Mammalian Cell Assay	(OPPTS 870.5300, 870.5375)

Tier II Studies

In vitro Mammalian Cytogenetics	(OPPTS 870.5385, 870.5395)
Prenatal Development	(OPPTS 870.3700)
Immunotoxicity	(OPPTS 880.3550)
Dermal Outdoor Exposure	(OPPTS 875.1100)
Dermal Indoor Exposure	(OPPTS 875.1200)
Inhalation Outdoor Exposure	(OPPTS 875.1300)
Inhalation Indoor Exposure	(OPPTS 875.1400)
Biological Monitoring	(OPPTS 875.1500)

Tier III Studies

Immune Response	(OPPTS 880.3800)
Reproduction and Fertility Effects	(OPPTS 870.3800)
Chronic Oral Toxicity	(OPPTS 870.4100)
Carcinogenicity	(OPPTS 870.4200)
Mammalian Spermatogonial Chromosome Aberration Testing	(OPPTS 870.5380)
Companion Animal Safety	(OPPTS 870.7200)

Registrant's Justification

Tier I

Acute Oral Toxicity

In mice, the LD_{50} for acetic acid is 4960 mg/kg (HPV, 2001).

Acute Dermal Toxicity

In rabbits, the LD_{50} for acetic acid is 1060 mg/kg (HPV, 2001).

Acute Inhalation Toxicity

In mice, the LC_{50} for acetic acid is 5620 ppm/hr; in rats, the LC_{50} for acetic acid is 11.4 mg/L (HPV, 2001).

Primary Eye Irritation

Due to the low pH and known corrosivity of the product, an acute eye irritation study is not required (EPA, 2008).

Primary Dermal Irritation

Due to the low pH and known corrosivity of the product, a primary dermal irritation study is not required (EPA, 2008).

Dermal Sensitization

Acetic acid is not a dermal sensitizer (EPA, 2008).

Hypersensitivity

The registrant is not aware of any hypersensitivity incidents, but will immediately report any such incidents.

90-Day Oral Toxicity

In a 90-day study where rats were administered up to 390 mg acetic acid/kg/day in drinking water for 2 to 4 months, the LOAEL was 390 mg/kg/day (based on weight loss), and the NOAEL was 195 mg/kg/day (EPA, 2008).

90-Day Dermal Toxicity

The use pattern does not include purposeful application to the skin.

90-Day Inhalation Toxicity

There is little likelihood of significant levels of repeated inhalation exposure to the product as a gas, vapor, or aerosol.

Prenatal Development

In rats receiving doses of 5% table strength apple cider vinegar up to 1600 mg/kg/day for 10 days, there were no effects on nidation or on maternal or fetal survival. In mice receiving doses of 5% table strength apple cider vinegar up to 1600 mg/kg/day for 17 days, there were no effects on nidation or on maternal or fetal survival. In rabbits receiving doses of 5% table strength apple cider vinegar up to 1600 mg/kg/day for 23 days, there were no effects on nidation or on maternal or fetal survival (HPV, 2001).

Bacterial Reverse Mutation Test

In three Ames tests using acetic acid with and without metabolic activation, no genotoxic effects were seen (HPV, 2001).

In vitro Mammalian Cell Assay

In Chinese hamster ovary K1 cells, acetic acid was not clastogenic at concentrations close to those showing cytotoxicity (HPV, 2001).

Tier II

In vitro Mammalian Cytogenetics

Since there were no mutagenic effects in Tier I studies, Tier II testing is not required.

Prenatal Development

Since there were no developmental effects in the Tier I studies, Tier II testing is not required.

Immunotoxicity

According to the Registration Review Summary Document for Acetic Acid and Salts (EPA, 2008), "…it is highly unlikely that acetic acid would induce adverse immune response in humans via the exposure levels expected from the proposed use of the products."

Dermal Outdoor Exposure/Dermal Indoor Exposure

No human health data indicate a potential hazard to the applicator/user.

Inhalation Outdoor Exposure/Inhalation Indoor Exposure

No human health data indicate a potential hazard to the applicator/user.

Biological Monitoring

No human health data indicate a potential hazard to the applicator/user.

Tier III

Immune Response

According to the Registration Review Summary Document for Acetic Acid and Salts (EPA, 2008), "...it is highly unlikely that acetic acid would induce adverse immune response in humans via the exposure levels expected from the proposed use of the products."

Reproduction and Fertility Effects

This study is not triggered by any results of the subchronic, prenatal development, or mutagenicity testing with acetic acid.

Chronic Oral Toxicity

This study is not required because there is no potential for adverse chronic effects indicated by subchronic testing, the use pattern, and the frequency and level of repeated human exposure.

Carcinogenicity

These studies are not required because 1) the active ingredient (or any of its metabolites, degradation products, or impurities) did not produce in Tier I subchronic studies a morphologic effect in any organ that could potentially lead to a neoplastic change, and 2) adverse cellular effects suggesting carcinogenic potential were not seen in a Tier II immunotoxicity study of Tier III immune response study, or in Tier II mammalian mutagenicity assays.

Mammalian Spermatogonial Chromosome Aberration Testing

Results from lower tier mutation or reproductive studies do not indicate potential for chromosomal aberration to occur.

Companion Animal Safety

Although the label allows application to animal enclosures, use of the product will not result in exposure to domestic animals through direct application or consumption of treated feed.

Reviewer's Comments

Sufficient information was submitted to support the requested waivers for Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation Toxicity, Primary Eye Irritation, Primary Dermal Irritation, Dermal Sensitization, Hypersensitivity, 90-Day Oral Toxicity, 90-Day Dermal Toxicity, 90-Day Inhalation Toxicity, Prenatal Development (Tier I), Bacterial Reverse Mutation Testing, *In vitro* Mammalian Cell Assay, *In vitro* Mammalian Cytogenetics, Prenatal Development (Tier II), Immunotoxicity, Dermal Outdoor Exposure, Dermal Indoor Exposure, Inhalation Outdoor Exposure, Inhalation Indoor Exposure, Biological Monitoring, Immune Response, Reproduction and Fertility Effects, Chronic Oral Toxicity, Carcinogenicity, Mammalian Spermatogonial Chromosome Aberration Testing, and Companion Animal Safety for Fleischmann's Vinegar Weed Control.

References

EPA, 2008. Acetic Acid and Salts Summary Document Registration Review: Initial Docket March 2008 Case # 4001, SRRD, OPP, USEPA.

HPV, 2001. U.S. High Production Volume (HPV) Chemical Challenge Program – Robust Summaries for Acetic Acid and Salts Category. American Chemistry Council, Acetic Acid and Salts Panel. June 28, 2001.

Acetic Acid
PC Code: 044001

DP Number: 366234
EPA Reg. No.: 85208-R

DATA EVALUATION RECORD

ACETIC ACID
(Fleischmann's Vinegar Weed Control)

STUDY TYPE: Waiver Requests for Nontarget Organism and Environmental Fate Data Requirements

MRID 47744704

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 09-025

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: _____
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Secondary Reviewers:
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Robert H. Ross, M.S., Group Leader

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Quality Assurance:
Lee Ann Wilson, M.A.

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Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA EVALUATION RECORD

EPA Secondary Reviewer:

STUDY TYPE:	Waiver Requests for Nontarget Organism and Environmental Fate Data Requirements
MRID NO:	47744704
DECISION NO:	409440
DP BARCODE:	DP365094
TEST MATERIAL:	Fleischmann's Vinegar Weed Control (a.i., 20.00 % w/w acetic acid)
PROJECT STUDY NO:	Not applicable
SPONSOR:	Fleischmann's Vinegar Co., Inc., 12604 Hiddencreek Way, Cerritos, CA 90703
TESTING FACILITY:	Not applicable
TITLE OF REPORT:	Fleischmann's Vinegar Weed Control: Nontarget Organisms and Environmental Fate
AUTHOR:	Norton, S.
STUDY COMPLETED:	May 1, 2009
CONFIDENTIALITY CLAIMS:	None.
GOOD LABORATORY PRACTICE:	A signed and dated GLP statement was included. The submitter was not the sponsor, did not conduct the studies, and does not know if the studies were conducted in accordance with 40 CFR Part 160.
CONCLUSION:	Sufficient information was submitted to support the requested waivers for Avian Acute Oral Toxicity, Avian Dietary Toxicity, Freshwater Fish Acute Toxicity, Freshwater Aquatic Invertebrate Acute Toxicity, Nontarget Insect Testing, Sediment and Soil Absorption/Desorption, Soil Column Leaching, Laboratory Volatilization from Soil, Hydrolysis, Aerobic Soil Metabolism, Photodegradation in Water, Photodegradation on Soil, Anaerobic Soil Metabolism, Aerobic Aquatic Metabolism, Anaerobic Aquatic Metabolism, Dispenser – Water Leaching, Freshwater Fish/Invertebrate Testing, Marine/Estuarine/Fish/Invertebrate Animal Testing, Aquatic Field/Fish/Invertebrate Testing, Avian Reproduction, Wild Mammal Acute Toxicity, Terrestrial Field Testing, Field Testing for Pollinators, and Nontarget Plant Testing for Fleischmann's Vinegar Weed Control. Studies for Seedling Emergence and Vegetative Vigor will need to be conducted. The registrant requests regulatory treatment consistent with that for registered acetic acid herbicides.

Product Description

Fleischmann's Vinegar Weed Control (white distilled vinegar) is an end use product for non-selective control of herbaceous broadleaf weeds and weed grasses on residential, non-crop, right-of-way, and industrial land sites. The active ingredient is 20.00% w/w acetic acid. Impurities associated with the active ingredient are [redacted] and [redacted]. The inert ingredient is [redacted]

Waiver Request

The registrant is requesting waivers for the following studies:

Tier I Studies

Avian Acute Oral Toxicity	(OPPTS 850.2100)
Avian Dietary Toxicity	(OPPTS 850.2200)
Freshwater Fish Acute Toxicity	(OPPTS 850.1075)
Freshwater Aquatic Invertebrate Acute Toxicity	(OPPTS 850.1010)
Seedling Emergence	(OPPTS 850.4100)
Vegetative Vigor	(OPPTS 850.4150)
Nontarget Insect Testing	(OPPTS 850.4350)

Tier II Studies

Sediment and Soil Absorption/Desorption	(OPPTS 835.1230)
Soil Column Leaching	(OPPTS 835.1240)
Laboratory Volatilization from Soil	(OPPTS 835.1410)
Hydrolysis	(OPPTS 835.2120)
Aerobic Soil Metabolism	(OPPTS 835.4100)
Photodegradation in Water	(OPPTS 835.2240)
Photodegradation on Soil	(OPPTS 835.2410)
Anaerobic Soil Metabolism	(OPPTS 835.4200)
Aerobic Aquatic Metabolism	(OPPTS 835.4300)
Anaerobic Aquatic Metabolism	(OPPTS 835.4400)
Dispenser – Water Leaching	(OPPTS 880.4425)
Seedling Emergence	(OPPTS 850.4225)
Vegetative Vigor	(OPPTS 850.4250)

Tier III Studies

Freshwater Fish/Invertebrate Testing	(OPPTS 850.1300, 850.1400, 850.1500)

Marine/Estuarine/Fish/Invertebrate Animal Testing	(OPPTS 850.10025, 850.1035, 850.1045, 850.1055, 850.1350, 850.1400, 850.1500)
Aquatic Field/Fish/Invertebrate Testing	(OPPTS 850.1950)
Avian Reproduction	(OPPTS 850.2300)
Wild Mammal Acute Toxicity	(OPPTS 850.2400)
Terrestrial Field Testing	(OPPTS 850.2500)
Field Testing for Pollinators	(OPPTS 850.3040)
Nontarget Plant Testing	(OPPTS 850.4225, 850.4250, 850.4300, 850.4450)

Registrant's Justification

Tier I

Avian Acute Oral Toxicity

The Registration Review Summary Document for Acetic Acid and Salts (EPA, 2008) did not indicate avian acute oral toxicity data are needed.

The proposed product label states "Do not apply to roosting or nesting birds…"

Avian Dietary Toxicity

The Registration Review Summary Document for Acetic Acid and Salts (EPA, 2008) did not indicate avian dietary toxicity data are needed.

The proposed product label states "Do not apply to roosting or nesting birds…"

Freshwater Fish Acute Toxicity

The 96-hr LC_{50} for acetic acid in bluegill sunfish (*Lepomis macrochirus*) was 75 mg/L. The 96-hr LC_{50} in mosquito fish (*Gambusia affinis*) was 251 mg/L (HPV, 2001).

The proposed product label states "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate."

Freshwater Aquatic Invertebrate Acute Toxicity

The static 24-hr LC_{50} for acetic acid in *Daphnia magna* was 47 mg/L. For acetic acid solution neutralized to pH 8.0, the 24-hr EC_{50} in *D. magna* using immobility as the endpoint was 6000 mg/L. Without neutralization, the 24-hr EC_{50} using immobility as the endpoint was 95 mg/L. The 48-hr EC_{50} using immobility as the endpoint was 65 mg/L (apparently without neutralization) (HPV, 2001).

The proposed product label states "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate."

Seedling Emergence/Vegetative Vigor

The Registration Review Summary Document for Acetic Acid and Salts (EPA, 2008) indicates this requirement is a data gap, and that data will be required via a data call-in. The registrant requests regulatory treatment consistent with that for registered acetic acid herbicides.

Nontarget Insect Testing

The Registration Review Summary Document for Acetic Acid and Salts (EPA, 2008) mentions that two unreviewed nontarget insect studies are in EPA files, but does not request review of those studies or submission of any data.

The proposed product label includes the following statement: "Do not apply … to flowering plants during times of day when bees are actively foraging." If a waiver is not granted, the registrant requests a regulatory treatment consistent with that for registered acetic acid herbicides.

Tier II

Sediment and Soil Absorption/Desorption

Not required, since Tier I studies do not indicate adverse effects.

Soil Column Leaching

Not required, since Tier I studies do not indicate adverse effects.

Laboratory Volatilization from Soil

Not required, since Tier I nontarget organisms data do not indicate adverse effects.

Hydrolysis

Not required, since Tier I studies do not indicate adverse effects.

Aerobic Soil Metabolism

Not required, since Tier I studies do not indicate adverse effects.

Photodegradation in Water/Photodegradation on Soil

Not required, since Tier I studies do not indicate adverse effects.

Anaerobic Soil Metabolism

Not required, since Tier I studies do not indicate adverse effects.

Aerobic Aquatic Metabolism/Anaerobic Aquatic Metabolism

Not required, since Tier I studies do not indicate adverse effects.

Dispenser – Water Leaching

Not required, since the product is not to be applied in a passive dispenser.

Seedling Emergence

The Registration Review Summary Document for Acetic Acid and Salts (EPA, 2008) indicates this requirement is a data gap, and that data will be required via a data call-in. The registrant requests regulatory treatment consistent with that for registered acetic acid herbicides.

Vegetative Vigor

The Registration Review Summary Document for Acetic Acid and Salts (EPA, 2008) indicates this requirement is a data gap, and that data will be required via a data call-in. The registrant requests regulatory treatment consistent with that for registered acetic acid herbicides.

Tier III

Freshwater Fish/Invertebrate Testing

The Registration Review Summary Document for Acetic Acid and Salts (EPA, 2008) concludes that "At current label uses, risks to aquatic organisms from these uses are expected to be

minimal, since contamination of aquatic environments from runoff will only result in short-term pH changes that will be counteracted by the natural buffering capacity of the water and soil."

Marine/Estuarine Fish/Invertebrate Testing

The Registration Review Summary Document for Acetic Acid and Salts (EPA, 2008) concludes that "At current label uses, risks to aquatic organisms from these uses are expected to be minimal, since contamination of aquatic environments from runoff will only result in short-term pH changes that will be counteracted by the natural buffering capacity of the water and soil."

Aquatic Field Fish/Invertebrate Testing

The Registration Review Summary Document for Acetic Acid and Salts (EPA, 2008) concludes that "At current label uses, risks to aquatic organisms from these uses are expected to be minimal, since contamination of aquatic environments from runoff will only result in short-term pH changes that will be counteracted by the natural buffering capacity of the water and soil."

Avian Reproduction

The Registration Review Summary Document for Acetic Acid and Salts (EPA, 2008) does not identify this as a data requirement that needs to be filled.

Wild Mammal Acute Toxicity

The Registration Review Summary Document for Acetic Acid and Salts (EPA, 2008) does not identify this as a data requirement that needs to be filled.

Terrestrial Field Testing

The Registration Review Summary Document for Acetic Acid and Salts (EPA, 2008) does not identify this as a data requirement that needs to be filled.

Field Testing for Pollinators

The Registration Review Summary Document for Acetic Acid and Salts (EPA, 2008) does not identify this as a data requirement that needs to be filled.

Nontarget Plant Studies

The Registration Review Summary Document for Acetic Acid and Salts (EPA, 2008) does not identify this as a data requirement that needs to be filled.

Reviewer's Comments

Sufficient information was submitted to support the requested waivers for Avian Acute Oral Toxicity, Avian Dietary Toxicity, Freshwater Fish Acute Toxicity, Freshwater Aquatic Invertebrate Acute Toxicity, Nontarget Insect Testing, Sediment and Soil Absorption/Desorption, Soil Column Leaching, Laboratory Volatilization from Soil, Hydrolysis, Aerobic Soil Metabolism, Photodegradation in Water, Photodegradation on Soil, Anaerobic Soil Metabolism, Aerobic Aquatic Metabolism, Anaerobic Aquatic Metabolism, Dispenser – Water Leaching, Freshwater Fish/Invertebrate Testing, Marine/Estuarine/Fish/Invertebrate Animal Testing, Aquatic Field/Fish/Invertebrate Testing, Avian Reproduction, Wild Mammal Acute Toxicity, Terrestrial Field Testing, Field Testing for Pollinators, and Nontarget Plant Testing for Fleischmann's Vinegar Weed Control. Studies for Seedling Emergence and Vegetative Vigor will need to be conducted. The registrant requests regulatory treatment consistent with that for registered acetic acid herbicides.

References

EPA, 2008. Acetic Acid and Salts Summary Document Registration Review: Initial Docket March 2008 Case # 4001, SRRD, OPP, USEPA.

HPV, 2001. U.S. High Production Volume (HPV) Chemical Challenge Program – Robust Summaries for Acetic Acid and Salts Category. American Chemistry Council, Acetic Acid and Salts Panel. June 28, 2001.